K080446

X. PREMARKET NOTIFICATION SUMMARY

NOV 2 6 2008

Submitted by:

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Contact Person:

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Date Prepared:

25 November 2008

Trade Name:

RapidVit™ Cleave
RapidWarm™ Cleave

Common Name:

Vitrification freeze kit for cleavage stage embryos
Vitrification warming kit for cleavage stage embryos

Classification Name:

Reproductive Media and Supplements
(21 C.F.R. § 884.6180)

Predicate Device:

Vit Kit™ - Freeze and Vit Kit™ - Thaw from Irvine Scientific Co., Inc. (K060168)

Description of the Device:

RapidVit™ Cleave is used for vitrification of day 3 cleavage stage embryos. The cryoprotectants 1,2-propanediol and ethylene glycol are used together with sucrose for dehydration of the embryo before cryopreservation. Then the embryos are

	immediately plunged into liquid nitrogen in order to prevent intracellular and extracellular ice crystal formation. RapidWarm™ Cleave is used for the subsequent warming of vitrified day 3 cleavage stage embryos
Intended Use:	RapidVit™ Cleave is intended for vitrification of day 3 cleavage stage embryos RapidWarm™ Cleave is intended for warming of vitrified day 3 cleavage stage embryos

Technological Characteristics:

RapidVit™ Cleave and RapidWarm™ Cleave are devices used for vitrification of day 3 cleavage stage embryos. The cryoprotectants 1,2-propanediol and ethylene glycol are used together with sucrose for dehydration of the embryo before cryopreservation. Then the embryos are immediately plunged into liquid nitrogen in order to prevent intracellular and extracellular crystal formation.

The predicate device Vit Kit™ - Freeze/Vit Kit™ - Thaw and RapidVit™ Cleave/RapidWarm™ Cleave are embryo-physiological solutions supplemented with permeable and non-permeable cryoprotectants. Both devices are subject to the same control methods and, to a significant degree, contain the same components. They have similar handling procedures and the same sterility assurance level (10^{-3}) and storage conditions.

The main differences between RapidVit™ Cleave and RapidWarm™ Cleave and Vit Kit™ - Freeze and Vit Kit™ - Thaw are the following:

- Vit Kit™ - Freeze and Vit Kit™ - Thaw contain ethylene glycol, DMSO and sucrose as cryoprotectants, while RapidVit™ Cleave and RapidWarm™ Cleave contain ethylene glycol, 1,2-propanediol and sucrose

- Vit Kit™ - Freeze and Vit Kit™ - Thaw is intended for blastocysts stage embryos while RapidVit™ Cleave and RapidWarm™ Cleave is intended for cleavage stage embryos

Successful vitrification of human cleavage stage embryos by use of RapidVit™ Cleave and RapidWarm™ Cleave has been clinically proven (Balaban et al. 2008).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kjell Kjörk
Pharmacist, Regulatory Affairs Manager
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SWEDEN

NOV 2 6 2008

Re: K080446
Trade/Device Name: RapidVit™ Cleave
RapidWarm™ Cleave
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: November 10, 2008
Received: November 12, 2008

Dear Mr. Kjörk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K080446

XI. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080446

Device Name: RapidVit™ Cleave
RapidWarm™ Cleave

Indications for Use:

RapidVit™ Cleave is indicated for vitrification of day 3 cleavage stage embryos

RapidWarm™ Cleave is indicated for warming of vitrified day 3 cleavage stage embryos

RapidVit™ Cleavage and RapidWarm™ Cleavage are restricted to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the Counter Use

(Per 21 C.F.R. § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080446